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26389	7590	05/05/2004	EXAMINER	
CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC			LU, FRANK WEI MIN	
1420 FIFTH AVENUE			ART UNIT	
SUITE 2800			PAPER NUMBER	
SEATTLE, WA 98101-2347			1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/934,778

Applicant(s)

CROTEAU ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 11, and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3/2004.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 10-18 and species (1) (angiosperm geranyl diphosphate synthase large subunit protein, claim 11) filed on March 8, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, claims 10, 11, and 13-18 will be examined.

Specification

2. The disclosure is objected to because of the following informality: "Patent No. 5,8876,964" in the first sentence of the specification should be "Patent No. 5,876,964".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 10, 11, 13-15, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicant is referred to the interim guidelines on written description published on December 21, 1999 in the Federal Register at Volume 64, Number 244, pp.71427-71440.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

The specification (page 32-49) provides adequate written description for an isolated, recombinant *Mentha piperita* geranyl diphosphate synthase large subunit, which is a key enzyme for monoterpene synthesis in plant cells (see The Plant Journal, 24, 241-252, 2000). However, the specification fails to adequately describe any kind of recombinant geranyl diphosphate synthase large subunit. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998).

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In this instant case, claim 10 is read as any kind of isolated, recombinant diphosphate synthase large subunit. Claim 11 is read as any kind of isolated, recombinant, angiosperm geranyl diphosphate synthase large subunit. Claim 13 is read as any kind of isolated, recombinant oil plant geranyl diphosphate synthase large subunit. Claim 14 is read as any kind of isolated, recombinant Lamiaceae, geranyl diphosphate synthase large subunit. Claim 15 is read as any kind of isolated, recombinant *Mentha* geranyl diphosphate synthase large subunit. Claim 18 is read as any kind of isolated, recombinant diphosphate synthase comprising an isolated, recombinant diphosphate synthase large subunit and an isolated, recombinant diphosphate synthase small subunit. Although the specification adequately describes an isolated, recombinant *Mentha piperita* geranyl diphosphate synthase large subunit, the specification fails to adequately describe any kind of recombinant geranyl diphosphate synthase large subunit. Since claims 10 and 18 do not limit source of geranyl diphosphate synthase large subunit, from the specification, it is unclear whether any kind of organism in claims 10 and 18 has a geranyl diphosphate synthase large subunit or has a geranyl diphosphate synthase large subunit and a geranyl diphosphate synthase small subunit. Since claims 11, 13, and 14 do not limit that geranyl diphosphate synthase large subunit is from a specific plant, from the specification, it is unclear whether any kind of angiosperm in claim 11 or any kind of essential oil plant in claim 13 or any kind of Lamiaceae in claim 14 has a geranyl diphosphate synthase large subunit. Since claim 15 does not limit that geranyl diphosphate synthase large subunit is from a specific species of *mentha*, from the specification, it is unclear whether any kind of *mentha* in claim 15 has a geranyl diphosphate synthase large subunit. Therefore, claims 10, 11, 13-15, and 18 encompass numerous unknown and unidentified polypeptides that miss from the disclosure. From the

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specification, it is unclear whether these unknown and unidentified polypeptides that miss from the disclosure exist in nature since the specification does not provide evidence to show that any kind of organism has geranyl diphosphate synthase large subunit. Therefore, the general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

With limited disclosure provided by the specification, the skilled artisan cannot envision all above possible polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated, recombinant, *Mentha piperita* diphosphate synthase large subunit as recited in claims 16 and 17 meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 11 and 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 11 recites the limitation “angiosperm geranyl diphosphate synthase large subunit” in the claim. There is insufficient antecedent basis for this limitation in the claim since claim 10 does not limit that geranyl diphosphate synthase large subunit is an angiosperm geranyl diphosphate synthase large subunit. Please clarify.

8. Claim 12 recites the limitation “essential oil plant geranyl diphosphate synthase large subunit” in the claim. There is insufficient antecedent basis for this limitation in the claim since claim 10 does not limit that geranyl diphosphate synthase large subunit is an essential oil plant geranyl diphosphate synthase large subunit. Please clarify.

9. Claim 14 recites the limitation “Lamiaceae, geranyl diphosphate synthase large subunit” in the claim. There is insufficient antecedent basis for this limitation in the claim since claim 10 does not limit that geranyl diphosphate synthase large subunit is a Lamiaceae, geranyl diphosphate synthase large subunit. Please clarify.

10. Claim 15 recites the limitation “*Mentha* geranyl diphosphate synthase large subunit” in the claim. There is insufficient antecedent basis for this limitation in the claim since claim 10 does not limit that geranyl diphosphate synthase large subunit is a *Mentha* geranyl diphosphate synthase large subunit. Please clarify.

11. Claims 16 and 17 recite the limitation “*Mentha piperita* geranyl diphosphate synthase

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large subunit" in the claim. There is insufficient antecedent basis for this limitation in the claim since claim 10 does not limit that geranyl diphosphate synthase large subunit is a *Mentha piperita* geranyl diphosphate synthase large subunit. Please clarify.

Conclusion

12. No claim is allowed.


13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703)872-9306 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
April 30, 2004


FRANK LU
PATENT EXAMINER